Serial Number: 10/576,816 Filing Date: April 24, 2006

REMARKS

Claims 12-17, 19 and 21-33 are pending in the present application. Claims 22-31 are withdrawn from consideration. Claims 12-17, 19, 21, 32 and 33 are rejected.

Docket: C 2874 PCT/US

In the present amendment, claims 32 and 33 are amended to recite a lipophilic extract from the pulp of *Argania spinosa* fruit. Support for this amendment is found in the Substitute Specification, for example at page 10, lines 21-24 and at page 42, line 28 to page 43, line 1. Claim 19 is amended to correct a typographical error. No new matter is introduced and entry of the amendments is requested.

Rejections Under 35 USC 103(a)

Claims 14-17, 19, 21, and 32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chernane et al. (Phenolic composition of the pulp of fruits of argan (Argania spinosa) in relation to morphological characteristics Composition phenolique de la pulpe des fruits d'arganier (Argania spinosa L. Skeels) et relation avec leurs caracteristiques morphologiques, Agrochimica, (1999) Vol. 43, No. 3/4, pp. 137-150), in view of Basu-Modak et al. (Epicatechin and its methylated metabolite attenuate UVA-induced oxidative damage to human skin fibroblasts, Free radical biology & medicine, (2003 Oct 15) Vol. 35, No.8, pp. 910-21), and further in view of Katiyar et al. (Green tea polyphenolic antioxidants and skin photoprotection (review), International Journal of Oncology 18: 1307-1313,2001).

Chernane et al. is relied upon for teaching characterization of phenolic compounds of argan fruit pulp and that ripe argan fruit contains catechin. The Office Action admits that Chernane et al. do not teach a method of treating skin damage by applying to skin a solvent extract of the pulp of Argania spinasa fruit and at least one dermopharmaceutical auxiliary and/or additive, or the claimed amounts of such auxiliaries and additives. Basu-Modak et al. is relied upon for teaching that epicatechin and its metabolite protect fibroblasts against UVA damage and cell death. Katiyar et al. is relied upon for teaching that topical treatment with green tea polyphenols (including epicatechins) or EGCG before UVB exposure reduced UVB-induced erythema in human skin. It is concluded that it would have been obvious to apply extract from pulp

Serial Number: 10/576,816 Filing Date: April 24, 2006

of Argania spinasa fruit containing epicatechin to skin to treat skin damage caused by UV-A and UV-B.

Docket: C 2874 PCT/US

As amended, independent claim 32 recites a <u>lipophilic</u> extract of the pulp of *Argania spinosa* fruit. Such lipophilic extracts may be obtained, for example, using hexane or supercritical carbon dioxide as recited in claim 33. In contrast, Chernane discloses Argan fuit pulp extracts that are obtained by extraction with highly polar aqueous methanol and therefore contain polar substances such as phenolic compounds such as catechin. Chernane's polar extract will necessarily have a substantially different composition than the lipophilic extract of the invention.

Specifically, the lipophilic extract of the invention includes triterpenes, i.e., isoprene-containing compounds which would not be expected in a highly polar extract such as Chernane's. See page 42, line 28 to page 43, line 26 of the Substitute Specification. Chernane makes no mention of any such lipophilic component in the polar extract of the reference. Bau-Modak et al. and Katiyar et al. are relied upon in the reasoning of the rejection only to add teachings concerning the properties of polyphenolic compounds such as those taught by Chernane. Therefore, the combined references fail to teach or suggest any lipophilic extract or its use for treating skin damaged by UV-A and/or UV-B radiation.

To establish *prima facie* obviousness, all claim limitations must be taught or suggested by the prior art. *See In re Royka,* 490 F.2d 981, 985, 180 USPQ 580 (CCPA 1974). Furthermore, although the analysis need not identify explicit teachings directed to the claimed subject matter, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the lements in the way the claimed new invention does.: *KSR Int'l Co. v. Teleflex Inc.,* 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007). As such, "'there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *Id.* (quoting *In re Kahn,* 441 F.3d 977, 988, 78 USPQ2d, 1329, 1336 (Fed. Cir. 2006). A person of ordinary skill in this field knows that an extract of substantially different extract composition would be obtained by substituting a lipophilic extraction method for the polar extraction method of Chernane. The present rejection provides no articulated

reasoning that would have prompted the person of ordinary skill to make such a change in extraction methods. *Prima facie* obviousness has therefore not been established and withdrawal of the rejection is requested.

Docket: C 2874 PCT/US

Claims 12-17, 19-21 and 32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Chernane et al., Basu-Modak et al. and Katiyar et al. as applied to claims 14-17, 19, 21, and 32 above, and further in view of Charrouf et al. (Triterpenes and sterols isolated from the pulp of Argania spinosa (L.), Sapotaceae, Plantes Medicinales et Phytotherapie 25 (203), 112-117,1991) (full translation attached). Charrouf et al. is relied upon for teaching that triterpenic alcohols and sterols are found in the unsaponifiable fraction of a lipidic extract of *Argania spinosa*.

Charrouf et al. teach that Argan oil is used in traditional medicine for <u>diseases</u> of the skin, including chickenpox and acne, and against skin aging. Charrouf et al. do not teach or suggest in any way that the lipidic extract containing triterpenic alcohols would be useful for treatment of skin damaged by UV-A and/or UV-B radiation. Further, there is no reason that a person of skill in the art would expect lipophilic compounds such as triterpenes to possess the same UV radiation-related properties as polar compounds such as the epicatechins and polyphenols disclosed by Chernane, Basu-Modak and Katiyar. There is therefore no motivation to make such a substitution and *prima facie* obviousness has not been established. Withdrawal of the rejection is requested.

Claim 33 is newly rejected under 35 U.S.C. 103(a) as being unpatentable over Chernane et al., Basu-Modak et al. and Katiyar et al. as applied to claims 14-17, 19,21, and 32 above, and further in view of Wang et al. (Extraction of tea polyphenol, Guangzhou Huagong (2001),29(4),27-29). Wang et al. is added to provide a teaching of extraction of tea polyphenols using supercritical carbon dioxide. Again, the combination of references relates entirely to polyphenols, which are polar compounds obtained by extraction in polar solvents. There is no teaching in any of the references of a lipophilic extract as claimed. The Examiner asserts that supercritical carbon dioxide extraction is known to be interchangeable with alcoholic extraction. No evidentiary support for this assertion is provided, and Applicants do not agree with the Examiner's assessment. Supercritical carbon dioxide itself is a relatively non-polar

Amendment and Response Under 37 CFR 1.114

Serial Number: 10/576,816 Filing Date: April 24, 2006

solvent, but it can be used for extraction of a variety of compounds. To do so, it is

Docket: C 2874 PCT/US

typically modified by addition of more or less polar reagents to make the extraction

environment more or less polar as required. For this reason, the characteristics of the

desired extract must be known in advance and the reaction conditions that produce the

desired extract must be tested and determined for each such extraction. A teaching of

reaction conditions for extraction of a polar compound using supercritical carbon dioxide

does not inform the practitioner of the conditions necessary for extraction of a lipophilic

compound using supercritical carbon dioxide. Wang therefore teaches only how to

obtain an extract of specific, polar polyphenolic compounds found in green tea. The

reference does not suggest, or even recognize, that a lipophilic extract containing

compounds such as triterpenes can be obtained or what reaction conditions would

produce such an extract. Prima facie obviousness has therefore not been established

and withdrawal of the rejection is requested.

CONCLUSION

Applicants submit that claims 12-17, 19 and 21-33 of the present patent

application are now in condition for allowance, and an action passing this case to issue

is respectfully requested. It is believed that no fees are due in connection with this

submission, however, if fees are found to be due, the Commissioner is authorized to

charge Deposit Account No. 50-3329. Please contact the undersigned by telephone if

there are any issues remaining in this case.

Respectfully submitted,

Dated: June 14, 2011

/Donna R. Fugit, Reg. No. 32,135/

Donna R. Fugit, Ph.D.

Reg. No. 32,135

DIEHL SERVILLA LLC 33 WOOD AVENUE SOUTH, SUITE 210 ISELIN, NEW JERSEY 08830

(732) 815-0404

FAX (732) 815-1330

8